K010974

JUN 1 8 2001

Summary of Safety and Effectiveness

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

California Medical Laboratories, Inc. subject device is considered substantially equivalent to the cited predicate device based upon substantially equivalent intended uses, as well as, substantially equivalent technologic characteristics including material, dimensional and performance specifications.

COMPANY AND CONTACT PERSON

California Medical Laboratories Inc.
1570 Sunland Lane
Costa Mesa, CA 92626
Michael Webb
General Manager, Operations

DEVICE NAME

California Medical Laboratories Inc. Retrograde Cardioplegia Cannula, Manual-Inflating with either Guidewire Stylet or Malleable Stylet

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

The claim of substantial equivalence is based upon the following device:

- Quest Medical's Retrograde Cardioplegia Cannula – RCCS, RCM-15

DESCRIPTION OF DEVICE

The subject devices cannula is made of flexible wire-reinforced silicone tubing consisting of one larger lumen for infusion of cardioplegia solution, one smaller lumen for inflation of the balloon and a second smaller lumen for pressure monitoring. A manually inflating low-pressure silicone balloon is mounted on the cannula shaft proximal to the infusion holes, to maintain cannula position when the balloon is inflated. Balloon inflation and deflation is achieved by manually injecting and withdrawing sterile saline solution. The cannula is provided with either a guidewire or malleable wire stylet to facilitate cannula placement.

STATEMENT OF INTENDED USE

The Retrograde Cardioplegia Cannula, Manual-Inflating is intended for use in the infusion of blood or cardioplegia solution into the coronary venous system.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Quest Medical Retrograde Cardioplegia Cannula is intended for perfuse blood or cardioplegia solutions into the coronary venous system.

STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

California Medical Laboratories, Inc subject device has technologic characteristics including material, dimensional and performance specifications, which are substantially equivalent to the predicate device. Performance characteristics include such testing as leak and burst evaluation, as well as, performance flow characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2001

Mr. Mehmet Bicakci
President
California Medical Laboratories, Inc.
1570 Sunland Lane
Costa Mesa, CA 92626

Re: K010974
Trade/Device Name: Retrograde Cardioplegia Cannula, Manual-Inflating, with Malleable or Guidewire Stylet
Regulation Number: 21 C.F.R. § 870.4210
Regulatory Class: II
Product Code: DWF
Dated: March 29, 2001
Received: April 2, 2001

Dear Mr. Bicakci:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: California Medical Laboratories Inc. Retrograde Cardioplegia Cannula, Manual-Inflating, with Malleable or Guidewire Stylet

Indications For Use: The Retrograde Cardioplegia Cannula, Manual-Inflating is indicated for the infusion of blood or cardioplegia solution into the coronary venous system.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010974

Prescription Use _____ **OR** **Over-The-Counter Use** _____ **Per 21 CFR 801.109**